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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,108	10/12/2005	Nobuo Mochizuki	20241/0203481-US0	8647
7278	7590	06/27/2008		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER HAYLIN, ROBERT H	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			06/27/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,108

**Applicant(s)**

MOCHIZUKI ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Status of the claims:** Claims 1-14 are currently pending. Claim 14 was newly presented. Claims 4, and 7-12 are held withdrawn.

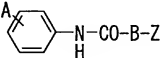
**Priority:** This application is a 371 of PCT/JP04/05237 04/13/2004 and claims foreign priority to JAPAN 2003-109667 (04/14/2003) and JAPAN 2004-023032 (01/30/2004).

**Declarations:** The declaration under 37 CFR 1.132 filed 2/15/2008 is insufficient to overcome the rejection of claims 1-3, 5, 6, 13 and 14 based upon 35 USC 103(a) as set forth in the last Office action because: the data presented do not show a direct comparison between the prior art compound and the elected species. Furthermore, the 30 mg/kg data only applies to compound 37 and not 3-19 AND the 100 mg/kg data only applies to compound 3-19 and not 37; thus the conclusion of unexpected results was not properly supported.

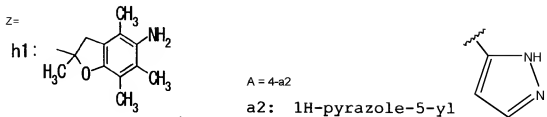
### *Election/Restrictions*

1. Applicant previously elected Group I (claims 1-3, 5, 6, and 13) in the reply filed on 9/19/07.

Applicant also elected the following species and claims 1-3, 5, 6, 13, 14 read thereupon:

Compound 37 which is described in Table 1 as: , wherein the

variables are defined: A is 4-a2; B is - ; and Z is h1. These variables are further defined such that:



As detailed below, the elected species was unpatentable and in accordance with the election of species practice described in the requirement for restriction, subject matter not reading on the elected species is hereby withdrawn.

## RESPONSE TO APPLICANT ARGUMENTS

### *Claim Rejections - 35 USC § 103*

2. Claims 1-3, 5, 6, and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda et al. (US 6,342,516 or “516” patent) in view of Hansch et al. (Substituent Constants for Correlation Analysis in Chemistry and Biology, (1979), Wiley, pages 1-63). This rejection is maintained and expanded to include claim 14 (reading on the elected species).

Applicant argues on page 20 that the teachings of Hansch are “merely an invitation to experiment” and cites to page 48 of the reference. However, on page 48 the reference explains the difficulty of the problem if the methodologies taught therein are NOT used. Because Hansch provides a systematic and numerical method to choose the specific substituents at a given site, the reference does teach a methodology that yields predictable results.

Applicant argues on page 20 that Hansch and ‘516 fail to suggest the unexpected effects of compound 37 as presented in the declaration. This argument is

not persuasive because the declaration was found unpersuasive as to unexpected results as detailed above.

Applicant argues on page 21 that compound 37 shows superior in vivo activity over control drugs 1 and 2. This was not found persuasive in the finding of obviousness over compound 3-19.

Applicant argues on page 22 that compound 37 shows unexpected results over the prior art. As discussed above, this argument is not persuasive because the data supporting the conclusion failed to make a direct comparison of the results.

#### ***Claim Objections***

Claim 1 was objected to because Formula 1 was not depicted in the claim. This objection was overcome by the claim amendment.

#### **NEW REJECTIONS**

##### ***Claim Rejections - 35 USC § 112***

3. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claim reads on a subgenus of the genus of claim 1 which does not have support in the original claims or the specification. Applicant argues in the remarks filed with the amendment that claim 14 specifically recites compound 37, however the variable B is not defined, thus this is a new subgenus.

***Conclusion***

4. No claims are in condition for allowance. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626